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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 02/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,352	MATTSSON, JENS	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 25, 2004 has been entered.

Consequently claims 1, 4, 6-7, 10-11, 14-15, and 17-26 are pending in the instant application.

Claim Rejections - 35 USC § 112

1. The rejection of claims 14-15 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of "essentially/substantially identical/preserved" is withdrawn in view of the cancellation of this phrase.

2. The rejection of claims 1, 4, 6-7, 10-11, 14-15, and 17-26 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants are asserting that the claims have been amended to recite an isolated mite protein comprising amino acids 1-83 of the sequence disclosed in SEQ ID NO: 2, a specific sequence, and therefore overcomes the rejection.

Applicants assertions have been fully considered but are not found to be fully persuasive.

Applicants are again reminded that they have disclosed only a fragment of a full length protein. The traditional starting amino acid, methionine, is absent from Applicants disclosure. Without this starting sequence information, Applicants specification describes only a single protein fragment (SEQ ID NO: 2) and based upon that single fragment species attempts to claim a full length i.e., any protein "comprising" amino acids 1-83 of SEQ ID NO: 2. It is these structural variants which have not been adequately described by the specification. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 2 alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. Furthermore, since SEQ ID NO: 2 is a fragment of a full length protein, the written description is only commensurate in scope with this fragment, thus the claims are only adequately described for "consisting of" the identified fragment, since additionally amino acids on the N or C terminus will have a profound effect on the activity of the protein.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

For reasons of record as well as the reasons set forth above, this rejection is maintained.

3. The rejection of claims 20-21 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic composition consisting of SEQ ID NO: 2 does not reasonably provide enablement for methods of treatment comprising administering compositions comprising SEQ ID NO: 2 is maintained.

It is noted that this rejection has been withdrawn from claim 19 in view of Applicants amendment to delete the phrase "for prevention...."

Applicants are asserting that the amendment to the claims overcomes the rejection.

Applicants arguments have been fully considered but are not found to be fully persuasive.

As set forth previously by Plotkin et al, those of skill in the art recognize that it is unpredictable whether a single protein derived from a pathogen will elicit protective

immunity. This is the type of immunity required by Applicants claims 20-21, i.e., for the ***treatment*** of a disease associated with mites. Thus, Factors 1, 4, 5 and 7 are all addressed by this teaching. Furthermore, Applicants specification provides no working examples of any treatment. (Factors 1 and 3).

Facts that should be considered in determining whether a specification is enabling, or if it would require an undue amount of experimentation to practice the invention include: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. See In re Wands, 858 F.2d 731,737, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988). The Federal Circuit has noted, however, that only those factors that are relevant based on the facts need to be addressed. See Enzo Biochem. Inc. v. Calgene, Inc. 188 F.3d 1362, 1371, 52 USPQ2d 1129, 1135 (Fed. Cir 1999).

The specification provides insufficient guidance of how to use the claimed polypeptides as a pharmaceutical for the treatment of disease. It is well recognized in the art that it is unclear whether a single protein derived from a pathogen will elicit protective immunity. Ellis, R.W. (see Chapter 29 of "VACCINES" [Plotkin, S.A et al.,(ed.), published by W.B. Saunders Company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] exemplifies this problem in the recitation that "The key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies ...and thus protect the host against attack by the pathogen."

In view of the lack of guidance, lack of examples, and lack of predictability associated with regard to producing and using the proteins encompassed in the scope of the claims one skilled in the art would be forced into undue experimentation in order to practice broadly the claimed invention.

For reasons of record, as well as the reasons set forth above this rejection is maintained.

4. The rejection of claim 25 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for recombinant host cells, does not reasonably provide enablement for all recombinant cells is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. The rejection of claim 6 under 35 U.S.C. 102(b) as being anticipated by Birkett is maintained.

Applicants are asserting that Birkett et al relate to the use of nitrate reductase gene as a selection marker. Applicants further assert that while the oligomers disclosed by Birkett et al include all possible combinations of nucleotide-hexamers, Birkett et al do not disclose or suggest the isolation of a nucleic acid as set forth in the claimed invention.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that Birkett et al relate to the use of nitrate reductase gene as a selection marker. However, the sole teaching relied upon by Birkett et al is of the random hexamer kit. It is this kit, solely, which anticipates the claim.

Finally, Applicants assert that while the oligomers disclosed by Birkett et al include all possible combinations of nucleotide-hexamers, Birkett et al do not disclose or suggest the isolation of a nucleic acid as set forth in the claimed invention. However, the claim recites an isolated nucleic acid which specifically hybridizes under stringent conditions to a nucleic acid which encodes amino acids 1-83 of SEQ ID NO: 2. Eighty three amino acids require a minimum nucleic acid sequence of 249 nucleotides. As stated by Applicants, the hexamer kit disclosed by Birkett contains every possible six consecutive nucleotide sequence. These hexamer sequences will hybridize to the 249 consecutive nucleic acid bases under the recited conditions set forth in the claim, given that multiple hexamer sequences will contain an exact match for six consecutive nucleotides. The hexamer nucleic acids found in the kit are already in isolated form.

Accordingly, the disclosure of the hexamer kit represents an isolated nucleic acid encompassed within the scope of the claim.

The claims are drawn to a nucleic acid which hybridizes specifically under stringent conditions to a nucleic acid according to claim 4.

Birkett et al (U.S. Patent Number 5,302,527) disclose of random priming with a mixed hexamer oligonucleotide kit (Multiprime Kit, Amersham). (See column 15 lines 25-30).

In view that Birkett disclose of oligomers containing every possible combination of nucleotides for 6 mers, and that these sequences will inherently hybridize to DNA encoding the protein of SEQ ID NO: 2 under the recited conditions, the disclosure of Birkett et al is deemed to anticipate the claimed invention.

For reasons of record as well as the reasons set forth above this rejection is maintained.

6. The rejection of claims 14-15 under 35 U.S.C. 102(e) as being anticipated by Hsu is maintained.

Applicants are asserting that the claims have been amended to no longer recite the term "analogue." Applicants further assert that Hsu fails to disclose or suggest a protein as set forth in the claimed invention.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants are again respectfully directed back to the claims. Claim 14 recites methods of screening a protein of claim 1 or a peptide "which exhibits antigenic properties essentially equivalent...". The protein disclosed by Hsu is deemed to reasonably be antigenically essentially equivalent in that both molecules are able to elicit an antibody. Accordingly, each and every limitation of the claims has been addressed.

The claims are directed to a method for screening a protein according to claim 1 or a peptide which exhibits antigenic properties essentially equivalent to said protein, which comprises the steps of producing a multiplicity of sample peptides and selecting a sample peptide with substantially the same structure to said protein or peptide which exhibits antigenic properties essentially equivalent to said protein.

Hsu (US Patent Number 6,171,800) disclose of evaluating compounds for the ability to inhibit or promote an interaction with a CAIP like family polypeptide. (See column 9).

In view that Hsu disclose of screening analogues for the ability to mimic the activity of a CAIP like polypeptide, the disclosure of Hsu is deemed to anticipate the claimed invention. It is noted that the claims further recite "antigenic properties essentially equivalent." Given that the proteins disclosed by Hsu are capable of eliciting an immune response, they are deemed to be essentially equivalent to those recited in the claims, and accordingly found to be anticipated.

For reasons of record as well as the reasons set forth above this rejection is maintained.

Claim Rejections - 35 USC § 112

7. The rejection of claim 6 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of Applicants amendment.

8. The rejection of claims 14-15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

The claims are vague and indefinite in the recitation of "A method for screening protein according to claim 1 ***or*** a peptide which exhibits...". Applicants amendment has created confusion, do they intend to claim a peptide? Or do they intend to claim a method of screening with the peptide? Furthermore, claim 15 now recites "wherein peptides comprise...". Is Applicant attempting to refer to both the peptide and protein or only the peptide? Clarification is requested.

The following new grounds of rejection are applied to the amended claims:

Claim Rejections - 35 USC § 112

9. Claims 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of "antigenic properties essentially equivalent" and "substantially the same structure." One of skill in the art would be unable to determine the metes and bounds of the claimed invention. For instance, what amount of divergence is permitted to still be considered essentially equivalent or substantially the same? Likewise, at what point is the divergence so severe as to no longer be encompassed by the phrase "essentially equivalent/substantially the same?" Without a clear definition as to the metes and bounds of the terms essentially the same and substantially the same, one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Navarro
Primary Examiner
February 16, 2005